

REMARKS

This Amendment After Final is submitted in the above-identified patent application in response to the Final Office Action mailed on October 14, 2003 ("Office Action"). Applicants respectfully request that the Amendment After Final be entered as it does not raise any new issues, and it places the above-identified patent application in condition for allowance or in better form for appeal.

Claims 8-23 are pending. The Office Action rejects Claims 8-23 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,536,511 ("*Yatka*"). Claims 8-11, 14-18 and 21-23 are rejected under 35 U.S.C §103(a) as being unpatentable over U.S. Patent No. 5,578,336 ("*Monte*"). In addition, Claims 8-23 are rejected under 35 U.S.C §103(a) as being unpatentable over *Monte* in view of *Yatka*. In response, Claims 8 and 15 have been amended. The claims have been amended in order to more clearly describe the present invention. Support for the amendments may be found on pages 8 and 9 of the Application; thus, no new matter has been added. Further, the amendments clearly do not present any new issues requiring further consideration or search by the Patent Office. Applicants respectfully submit that each of the cited references fails to teach or arguably suggest a number of the features of the claimed invention, and, therefore, all of the above-mentioned rejections have been overcome or are improper for reasons set forth below.

In the Office Action, Claims 8-23 are rejected under 35 U.S.C. § 102(b) as being anticipated by *Yatka*.

The present invention, as now claimed, provides a product having a chewable water insoluble center and a coating that surrounds the center. The coating comprises at least 50% by weight of the product and includes at least one medicament in an amount sufficient to cause a desired physiological effect.

Yatka relates to a chewing gum product comprising a gum pellet covered by a hard coating containing erythritol and xylitol. The Office Action admits that *Yatka* does not teach the use of medicament in the coating composition. See Office Action at 2. The Examiner states, however, that *Yatka* teaches the use of calcium carbonate, magnesium carbonate, and talc which are well-known minerals in the pharmaceutical art. According to the Examiner, such language

suggests the use of a medicament in the coating since Applicants' Claims 9 and 16 recited "minerals" as one of many medicaments that could be used in the coating.

Applicants respectfully submit that *Yatka* does not disclose the use of calcium carbonate, magnesium carbonate, and talc in a coating in an amount sufficient to cause a desired physiological effect. Calcium carbonate, magnesium carbonate, and talc as disclosed in *Yatka* are not used as medicaments but are used along with other substances as coating or panning modifiers. *See* Col. 4, lines 25-32. Panning modifiers act to stabilize the coating composition and improve its quality. More specifically *Yatka* discloses including calcium carbonate, magnesium carbonate, and talc in an amount sufficient to serve as anti-tack agents. *See* Col. 12, lines 56-58. Because *Yatka* does not disclose a coating having medicaments in an amount sufficient to cause a desired physiological effect, *Yatka* fails to anticipate the claimed invention.

Claims 8 to 11, 14 to 18 and 21 to 23 are rejected under 35 U.S.C §103(a) as being unpatentable over U.S. Patent No. 5,578,336 ("*Monte*"). In addition, Claims 8-23 are rejected under 35 U.S.C §103(a) as being unpatentable over *Monte* in view of *Yatka*. Applicants respectfully submit that these rejections are no longer proper in light of the amended claims.

Monte discloses a gum or soft candy center coated with at least two discrete coatings with different compositions: a first outer coating containing a vitamin or enzyme and a second outer coating sealingly separating the first coating from the center composition. *See* Col. 2, lines 3-10 and 44-52. The Office Action acknowledges that *Monte* does not teach or suggest a product comprising a coating which makes up at least 50% by weight of the product as claimed in Claim 8. The Office Action maintains, however, that it would have been obvious for one of skill in the art through routine experimentation to determine a suitable amount of coating to increase the sealing effect of the coating to protect the vitamins or enzymes from the moisture of the gum center. *See* p. 3 to 4 of Office Action. This teaching in *Monte* applies only to the second coating and not the first coating containing the vitamin. *Monte*, in fact, discloses spraying a coating of vitamins or enzymes over the sealing coating and does not suggest a coating which includes at least one medicament and which makes up at least 50% by weight of the product.

Claim 15 has been further amended such that the present invention includes a product comprising a coating that contacts the center. The coating includes at least one medicament in an amount sufficient to cause a desired physiological effect.

Monte does not teach or suggest a product comprising a coating that contacts the center. In fact, the teaching in *Monte* requiring a second coating to protect the coating containing the vitamin from the gum/candy center clearly constitutes a teaching away from the present invention. Thus, *Monte* not only does not suggest the amended claims and the claims that depend therefrom, it actually teaches away from same.

Moreover, there is no teaching, suggestion or motivation to combine *Monte* with *Yatka*. As a result, a person of ordinary skill in the art would not be inclined to modify *Monte* in view of *Yatka* to arrive at the claimed invention. The Office Action at page 4 bases the motivation to combine *Yatka* with *Monte* on an interpretation that the references teach the “advantageous results” in the use of sugar or sugarless sweeteners in a coating composition. *Monte*, however, merely teaches that “[a]t least one of the coatings typically comprises a plurality of hard and/or crunchy ‘pan’ coating layers of a sugar or sugarless sweetener.”

The use of a general characteristic such as the presence of a sweetener in a coating common to substantially all chewable products as the motivation to combine *Yatka* with *Monte* and, specifically, elements from these patents to form the claimed invention, without more, lacks the level of specificity required to make such a combination. It is well established that a specific motivation must be identified in the prior art to establish that there is adequate teaching or suggestion to combine the references to make the present invention. *In re Dembiczak*, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). Obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the claimed invention. *ATD Corp v. Lydall, Inc.*, 48 U.S.P.Q. 2d 1321, 1329 (Fed. Cir. 1998). When the Patent Office fails to explain how one of ordinary skill in the art would have been specifically motivated by the prior art to make the claimed combination, the court infers that the obviousness determination has been impermissibly made in hindsight. *In re Rouffet*, 47 USPQ2d 1453, (Fed. Cir. 1998), (citing *In re Gorman*, 18 U.S.P.Q. 2d 1885, 1888 (Fed. Cir. 1991)). It is respectfully submitted that the Office Action does not explain how or why the skilled artisan

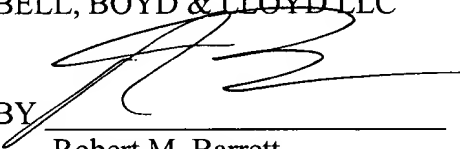
would have been specifically motivated to combine *Monte* with *Yatka*. Such combination of references relied upon by the Patent Office can only be gleaned from improper hindsight.

Applicants respectfully submit that the rejections based on 35 U.S.C. §§102 and 103 are each improper or have been overcome. Accordingly, Applicants respectfully submit that these rejections be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent application and earnestly solicit an allowance of same.

Respectfully submitted,

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Dated: January 14, 2004